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November 18, 2020

**VIA ELECTRONIC FILING**

The Honorable Colm F. Connolly  
United States District Judge  
J. Caleb Boggs Federal Building  
844 N. King Street  
Unit 31, Room 4124  
Wilmington, DE 19801-3555

Re: *Par Pharm., Inc. v. Eagle Pharm., Inc.*, C.A. No. 18-823-CFC-JLH

Dear Judge Connolly:

This firm, together with Kirkland & Ellis LLP, represents Defendant Eagle Pharmaceuticals, Inc. (“Eagle”) in the above-captioned matter. We write pursuant to the Court’s May 11, 2020 Oral Order (D.I. 182) regarding redactions to (1) Eagle’s October 27, 2020 Letter to Magistrate Judge Hall regarding the parties’ dispute over expert reports served after the close of fact discovery (D.I. 211) (“October 27 Letter”) and the exhibits thereto (D.I. 212) and (2) Eagle’s October 28, 2020 Letter to the Court regarding the status of its ANDA (D.I. 213) (“October 28 Letter”).

Eagle respectfully submits proposed redactions to these letters, along with the supporting Declaration of David Pernock (“Pernock Decl.”). The Pernock Declaration is filed contemporaneously hereto. So that this cover letter can remain public, the accompanying confidential Pernock Declaration explains the sensitive nature of Eagle’s confidential information in the letters and the harm that Eagle will suffer should that information be disclosed to the public. Versions of the October 27 Letter (D.I. 211) and October 28 Letter (D.I. 213), highlighted in yellow to show the specific redactions Eagle seeks, are being filed contemporaneously hereto as Exhibits A and B, respectively.<sup>1</sup> A version of the exhibits to the October 27 Letter (D.I. 212), highlighted in yellow to show the specific redactions Eagle seeks to

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<sup>1</sup> Exhibits A, B, and C were filed separately under seal so that this cover letter could be filed publicly.

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Exhibits 8–11, 15–16, and 18–20, are being filed contemporaneously hereto as Exhibit C. Eagle requests Exhibits 1–7 and 17 be sealed in their entirety. Eagle does not seek redaction to Exhibits 12–14 or 21–22. Eagle explains the bases for its proposed redactions below, as supported by the Pernock Declaration. Eagle respectfully requests that the Court allow the portions of the filings that Eagle has proposed to be redacted to remain under seal.

The remainder of the redactions to D.I. 211 and 212 (highlighted in blue) were proposed by Plaintiffs, and according to Plaintiffs, relate either to statements made in expert reports regarding information that Plaintiffs designated as “Confidential” or “Highly Confidential” under the terms of the Protective Order in this case, or to communications between counsel regarding Plaintiffs’ confidential information disclosed to Eagle under the terms of the Protective Order. As to D.I. 212, Plaintiffs requested Exhibits 1–20 be redacted in their entirety. Eagle takes no position on the additional redactions proposed by Plaintiffs.

For the Court’s convenience, public versions of the October 27 Letter, the exhibits thereto, and the October 28 Letter, with both Eagle’s and Plaintiffs’ proposed redactions included, are attached hereto as Exhibits D, E, and F, respectively.

\* \* \*

The limited information Eagle seeks to redact is the type of competitively sensitive, proprietary information that Eagle safeguards against disclosure. *See* Pernock Decl. ¶¶ 7–8, 12–13, 19. In particular, Eagle’s proposed redactions are tailored to those portions that disclose confidential information regarding the status of Eagle’s Abbreviated New Drug Application (“ANDA”) No. 211538, as well as the details concerning Eagle’s proposed ANDA Product and the results of Eagle’s confidential, internal testing. The information Eagle seeks to redact is not otherwise available to Eagle’s competitors or the public. Pernock Decl. ¶¶ 7, 12. Specifically, federal regulations require that the U.S. Food and Drug Administration (“FDA”) keep Eagle’s ANDA confidential until the application is finally approved. *See* 21 C.F.R. § 314.430; Pernock Decl. ¶ 7, 12. Further, Eagle’s business partners that have access to Eagle’s ANDA are under a contractual obligation to keep the application and related information confidential. Pernock Decl. ¶¶ 7, 12.

Courts have recognized that an unapproved ANDA and the information contained therein—such as the formulation of an unapproved ANDA Product, i.e., the same type of information Eagle seeks to redact—is “confidential under federal law.” *In re Gabapentin Litig.*, 312 F. Supp. 2d 653, 667 n.7 (D.N.J. 2004) (citing 21 C.F.R. § 314.430(b)–(d)); *id.* at 668 (noting that the formulation of a generic drug

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product is confidential information); *see also Bioavail Labs., Inc. v. Anchen Pharm., Inc.*, 463 F. Supp. 2d 1073, 1083 (C.D. Cal. 2006) (collecting cases discussing confidentiality of the formulation and composition of drug products). Courts have also recognized that the status of an unapproved ANDA is confidential and should be sealed during litigation to prevent disclosure. *See, e.g., Supernus Pharm., Inc. v. TWi Pharm., Inc.*, Civ. No. 15-369, slip op. at 6 (D.N.J. Sept. 21, 2017) (granting generic’s motion to seal because “the status of its ANDA with the FDA. . . is classically protected from public disclosure.”).

Moreover, as set forth in the accompanying Pernock Declaration, Eagle respectfully submits that public disclosure of the details concerning Eagle’s proposed ANDA Product and the results of Eagle’s confidential internal testing, as well as the status of Eagle’s ANDA, would cause substantial competitive harm to Eagle. *See* Pernock Decl. ¶¶ 8–11, 13–18; *Littlejohn v. Bic Corp.*, 851 F.2d 673, 678 (3d Cir. 1988) (courts may “deny access to judicial records, for example, where they are sources of business information that might harm a litigant’s competitive standing” (citation omitted)).

Eagle is mindful of the Court’s desire to permit public access to judicial proceedings, including the public’s ability to understand these proceedings. Eagle respectfully submits, however, that the sensitivity of the confidential information set forth in the limited redactions Eagle seeks weighs in favor of redaction, and allowing Eagle to maintain the confidentiality of this information will not affect the public’s ability to understand the proceeding. *See, e.g., Supernus*, slip op. at 8 (“[T]he Court agrees with TWi that there is little to no legitimate public interest in the public disclosure of TWi’s sensitive information, including . . . the confidential status of its ANDA with the FDA.”).

\* \* \*

Eagle respectfully requests that the Court permit these redactions to the public versions of the October 27 Letter (D.I. 211), exhibits thereto (D.I. 212), and October 28 Letter (D.I. 213).

Respectfully,

/s/ Bindu A. Palapura

Bindu A. Palapura

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Enclosures

cc: Clerk of the Court (via hand delivery)  
Counsel of Record (via electronic mail)